



Clinical trial results:

Three-, Five-, and Ten-Year Data on the Long-Term Immunogenicity of Tetanus and Diphtheria Toxoids Adsorbed Combined with Component Pertussis Vaccine and Inactivated Poliomyelitis Vaccine (TdcP-IPV) in Adolescents 11–14 Years of Age

Summary

EudraCT number	2015-005196-24
Trial protocol	Outside EU/EEA
Global end of trial date	04 June 2009

Results information

Result version number	v1 (current)
This version publication date	16 April 2016
First version publication date	16 April 2016

Trial information

Trial identification

Sponsor protocol code	TD9809-LT
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02040636
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Sanofi Pasteur Limited
Sponsor organisation address	1755 Steeles Ave. West, Toronto, Canada, M2R 3T4
Public contact	Clinical Team Leader, Sanofi Pasteur Limited, 1 416-667-2273, Miggi.Tomovici@sanofipasteur.com
Scientific contact	Clinical Team Leader, Sanofi Pasteur Limited, 1 416-667-2273, Miggi.Tomovici@sanofipasteur.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	04 June 2009
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	04 June 2009
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

1. The objective of this study was to describe the antibody levels for tetanus, diphtheria, pertussis and polio at 3 years, 5 years, and 10 years after vaccination with TdcP-IPV Vaccine.

Protection of trial subjects:

Subjects were vaccinated in a previous study, Td9809. No vaccination was administered as part of this long-term immunogenicity follow-up study.

Background therapy:

In Td9809, subjects were randomized to receive either Tetanus and Diphtheria Toxoids Adsorbed and Component Pertussis Vaccine Combined with Inactivated Poliomyelitis Vaccine (TdcP-IPV) followed by Hepatitis B vaccine one month later or TdcP-IPV vaccine and Hepatitis B vaccine concomitantly. For the long-term follow-up study, subjects in both groups were recalled for serology at 3, 5, and 10 years.

Evidence for comparator: -

Actual start date of recruitment	23 January 2002
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 277
Worldwide total number of subjects	277
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	101
Adolescents (12-17 years)	176

Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study subjects were enrolled from 23 January 2002 to 04 June 2009 at 1 clinic center in Canada.

Pre-assignment

Screening details:

A total of 277 subjects who met all inclusion and none of the exclusion criteria were enrolled in the long-term immunogenicity study.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

Not applicable

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1: Tdcp-IPV/Hepatitis B

Arm description:

Subjects received TdcP-IPV at month 0 and Hepatitis B at months 1, 2, and 7.

Arm type	Experimental
Investigational medicinal product name	Tetanus and Diphtheria Toxoids Adsorbed and Component Pertussis Vaccine with Inactivated Poliovirus (TdcP-IPV Vaccine)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL, intramuscular, 1 injection at Month 0.

Investigational medicinal product name	Hepatitis B Vaccine (Recombivax HB®)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL, intramuscular, 1 injection each at Months 1, 2, and 7.

Arm title	Group 2: Tdcp-IPV and Hepatitis B
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Arm description:

Subjects received TdcP-IPV and Hepatitis B at Month 0, Hepatitis B at months 1 and 6.

Arm type	Experimental
Investigational medicinal product name	Tetanus and Diphtheria Toxoids Adsorbed and Component Pertussis Vaccine with Inactivated Poliovirus (TdcP-IPV Vaccine)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL, intramuscular, 1 injection at Month 0.

Investigational medicinal product name	Hepatitis B Vaccine (Recombivax HB®)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL, intramuscular, 1 injection at Month 0 concurrent with TdcP-IPV and 1 injection each at Months 1 and 6.

Number of subjects in period 1	Group 1: Tdcp-IPV/Hepatitis B	Group 2: Tdcp-IPV and Hepatitis B
Started	144	133
Completed	91	83
Not completed	53	50
Lost to follow-up	53	50

Baseline characteristics

Reporting groups

Reporting group title	Group 1: Tdcp-IPV/Hepatitis B
Reporting group description:	
Subjects received TdcP-IPV at month 0 and Hepatitis B at months 1, 2, and 7.	
Reporting group title	Group 2: Tdcp-IPV and Hepatitis B
Reporting group description:	
Subjects received TdcP-IPV and Hepatitis B at Month 0, Hepatitis B at months 1 and 6.	

Reporting group values	Group 1: Tdcp-IPV/Hepatitis B	Group 2: Tdcp-IPV and Hepatitis B	Total
Number of subjects	144	133	277
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	48	53	101
Adolescents (12-17 years)	96	80	176
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	12.43	12.43	
standard deviation	± 0.83	± 0.95	-
Gender categorical			
Units: Subjects			
Female	75	60	135
Male	69	73	142

End points

End points reporting groups

Reporting group title	Group 1: Tdcp-IPV/Hepatitis B
Reporting group description:	
Subjects received TdcP-IPV at month 0 and Hepatitis B at months 1, 2, and 7.	
Reporting group title	Group 2: Tdcp-IPV and Hepatitis B
Reporting group description:	
Subjects received TdcP-IPV and Hepatitis B at Month 0, Hepatitis B at months 1 and 6.	

Primary: Percentage of Subjects with Seroprotection to Tetanus and Diphtheria Following Vaccination with Either TdcP-IPV or TdcP-IPV and Hepatitis B Vaccine Given Concurrently

End point title	Percentage of Subjects with Seroprotection to Tetanus and Diphtheria Following Vaccination with Either TdcP-IPV or TdcP-IPV and Hepatitis B Vaccine Given Concurrently ^[1]
End point description:	
Anti-Diphtheria antibody responses were measured using a micrometabolic inhibition test. Anti-Tetanus antibody responses were measured using an enzyme-linked immunosorbent assay (ELISA). Seroprotection was defined as post-vaccination antibody titers ≥ 0.01 IU/mL for Diphtheria and ≥ 0.01 EU/mL for Tetanus.	
End point type	Primary
End point timeframe:	
Day 0 (pre-vaccination) and 1 month and 3, 5, and 10 years post-vaccination	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Descriptive analyses were performed, based on the vaccine groups from the primary series for the long term follow-up period.

End point values	Group 1: Tdcp-IPV/Hepatitis B	Group 2: Tdcp-IPV and Hepatitis B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	144	132		
Units: Percentage of subjects				
number (not applicable)				
Diphtheria; Pre-vaccination	95.8	100		
Diphtheria; 1 month Post-vaccination	100	100		
Diphtheria; 3 years Post-vaccination	100	98		
Diphtheria; 5 years Post-vaccination	96.4	100		
Diphtheria; 10 years Post-vaccination	97.7	100		
Tetanus; Pre-vaccination	100	100		
Tetanus; 1 month Post-vaccination	100	100		
Tetanus; 3 years Post-vaccination	100	100		
Tetanus; 5 years Post-vaccination	100	100		
Tetanus; 10 years Post-vaccination	100	100		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects with Seroprotection to Tetanus and Diphtheria Following Vaccination with Either TdcP-IPV or TdcP-IPV and Hepatitis B Vaccine Given Concurrently

End point title	Percentage of Subjects with Seroprotection to Tetanus and Diphtheria Following Vaccination with Either TdcP-IPV or TdcP-IPV and Hepatitis B Vaccine Given Concurrently
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End point description:

Anti-Diphtheria antibody responses were measured using a micrometabolic inhibition test. Anti-Tetanus antibody responses were measured using an enzyme-linked immunosorbent assay (ELISA). Seroprotection was defined as post-vaccination antibody titers ≥ 0.1 IU/mL for Diphtheria and ≥ 0.1 EU/mL for Tetanus.

End point type	Other pre-specified
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End point timeframe:

Day 0 (pre-vaccination) and 1 month and 3, 5, and 10 years post-vaccination

End point values	Group 1: TdcP-IPV/Hepatitis B	Group 2: TdcP-IPV and Hepatitis B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	144	132		
Units: Percentage of subjects				
number (not applicable)				
Diphtheria; Pre-vaccination	63.2	67.4		
Diphtheria; 1 month Post-vaccination	98.6	100		
Diphtheria; 3 years Post-vaccination	83.6	82		
Diphtheria; 5 years Post-vaccination	49.1	47.9		
Diphtheria; 10 years Post-vaccination	57	54.3		
Tetanus; Pre-vaccination	99.3	100		
Tetanus; 1 month Post-vaccination	100	100		
Tetanus; 3 years Post-vaccination	100	100		
Tetanus; 5 years Post-vaccination	100	99		
Tetanus; 10 years Post-vaccination	100	97.1		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Summary of Geometric Mean Titers of Antibodies for Diphtheria and Tetanus Following Vaccination with Either TdcP-IPV or TdcP-IPV and Hepatitis B Vaccine Given Concurrently

End point title	Summary of Geometric Mean Titers of Antibodies for Diphtheria and Tetanus Following Vaccination with Either TdcP-IPV or TdcP-IPV and Hepatitis B Vaccine Given Concurrently
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End point description:

Anti-Diphtheria antibody responses were measured using a micrometabolic inhibition test. Anti-Tetanus antibody responses were measured using an enzyme-linked immunosorbent assay (ELISA).

End point type	Other pre-specified
End point timeframe:	
Day 0 (pre-vaccination) and 1 month and 3, 5, and 10 years post-vaccination	

End point values	Group 1: Tdcp-IPV/Hepatitis B	Group 2: Tdcp-IPV and Hepatitis B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	144	132		
Units: Titers (1/dil)				
geometric mean (confidence interval 95%)				
Diphtheria; Pre-vaccination	0.15 (0.12 to 0.19)	0.2 (0.16 to 0.25)		
Diphtheria; 1 month Post-vaccination	2.56 (2.11 to 3.11)	2.95 (2.48 to 3.5)		
Diphtheria; 3 years Post-vaccination	0.26 (0.21 to 0.32)	0.29 (0.22 to 0.37)		
Diphtheria; 5 years Post-vaccination	0.11 (0.09 to 0.13)	0.11 (0.09 to 0.14)		
Diphtheria; 10 years Post-vaccination	0.17 (0.13 to 0.23)	0.15 (0.12 to 0.2)		
Tetanus; Pre-vaccination	0.82 (0.71 to 0.94)	0.87 (0.75 to 1.01)		
Tetanus; 1 month Post-vaccination	19.54 (16.91 to 22.56)	17.4 (14.88 to 20.35)		
Tetanus; 3 years Post-vaccination	2.29 (1.99 to 2.64)	2.24 (1.9 to 2.64)		
Tetanus; 5 years Post-vaccination	1.4 (1.16 to 1.68)	1.48 (1.22 to 1.81)		
Tetanus; 10 years Post-vaccination	0.95 (0.76 to 1.2)	1.05 (0.83 to 1.34)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Summary of Geometric Mean Titers of Antibodies for Pertussis Following Vaccination with Either Tdcp-IPV or Tdcp-IPV and Hepatitis B Vaccine Given Concurrently

End point title	Summary of Geometric Mean Titers of Antibodies for Pertussis Following Vaccination with Either Tdcp-IPV or Tdcp-IPV and Hepatitis B Vaccine Given Concurrently
End point description:	
Anti-Pertussis (Pertussis toxoid, Filamentous hemagglutinin, Fimbriae types 2 and 3, and Pertactin) antibody responses were measured using an indirect enzyme-linked immunosorbent assay (ELISA).	
End point type	Other pre-specified
End point timeframe:	
Day 0 (pre-vaccination) and 1 month and 3, 5, and 10 years post-vaccination	

End point values	Group 1: Tdcp-IPV/Hepatitis B	Group 2: Tdcp-IPV and Hepatitis B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	144	132		
Units: Titers (1/dil)				
geometric mean (confidence interval 95%)				
Pertussis toxoid; Pre-vaccination	17.09 (13.69 to 21.35)	16.43 (12.91 to 20.92)		
Pertussis toxoid; 1 month Post-vaccination	267.87 (224.32 to 319.88)	222.63 (186.1 to 266.32)		
Pertussis toxoid; 3 years Post-vaccination	61.06 (49.44 to 75.4)	48.91 (39.25 to 60.95)		
Pertussis toxoid; 5 years Post-vaccination	47.99 (39.54 to 58.23)	42.11 (33.35 to 53.16)		
Pertussis toxoid; 10 years Post-vaccination	10.73 (8.24 to 13.97)	14.64 (10.73 to 19.98)		
Filamentous hemagglutinin; Pre-vaccination	33.53 (27.87 to 40.35)	39.93 (32.15 to 49.59)		
Filamentous hemagglutinin;1 month Post-vaccination	295 (255.11 to 341.13)	290.22 (252.95 to 332.97)		
Filamentous hemagglutinin;3 years Post-vaccination	64.95 (54.19 to 77.85)	59.77 (49.88 to 71.62)		
Filamentous hemagglutinin;5 years Post-vaccination	56.9 (47.61 to 68.01)	55.58 (46.51 to 66.42)		
Filamentous hemagglutinin;10 year Post-vaccination	33.3 (27.02 to 41.04)	36.9 (29.34 to 46.41)		
Pertactin; Pre-vaccination	10.49 (8.31 to 13.23)	13.36 (10.22 to 17.47)		
Pertactin; 1 month Post-vaccination	277.03 (220.45 to 348.13)	240.45 (196.47 to 294.27)		
Pertactin; 3 years Post-vaccination	62.38 (49.04 to 79.34)	63.74 (51.23 to 79.29)		
Pertactin; 5 years Post-vaccination	55.42 (43.57 to 70.49)	62.5 (49.7 to 78.6)		
Pertactin; 10 years Post-vaccination	26.66 (20.65 to 34.41)	36.96 (28.73 to 47.54)		
Fimbriae; Pre-vaccination	53.29 (42.27 to 67.2)	62.36 (49.99 to 77.78)		
Fimbriae; 1 month Post-vaccination	1414.97 (1166.02 to 1717.06)	1383.72 (1183.05 to 1618.43)		
Fimbriae; 3 years Post-vaccination	286.41 (237.06 to 346.02)	266.46 (219.76 to 323.09)		
Fimbriae; 5 years Post-vaccination	199.91 (166.25 to 240.38)	213.46 (178.04 to 255.93)		
Fimbriae; 10 years Post-vaccination	113.09 (92.99 to 137.54)	122.1 (99.5 to 149.82)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects with Seropositivity to Pertussis Antigens Following Vaccination with Either TdcP-IPV or TdcP-IPV and Hepatitis B Vaccine Given Concurrently

End point title	Percentage of Subjects with Seropositivity to Pertussis Antigens Following Vaccination with Either TdcP-IPV or TdcP-IPV and Hepatitis B Vaccine Given Concurrently
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End point description:

Anti-Pertussis (Pertussis toxoid, Filamentous hemagglutinin, Fimbriae types 2 and 3, and Pertactin) antibody responses were measured using an indirect enzyme-linked immunosorbent assay (ELISA). Seropositivity rates, defined as the percentage of subjects with post-vaccination titers $\geq$ lower limit of quantitation.

End point type	Other pre-specified
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End point timeframe:

Day 0 (pre-vaccination) and 1 month and 3, 5, and 10 years post-vaccination

End point values	Group 1: Tdcp-IPV/Hepatitis B	Group 2: Tdcp-IPV and Hepatitis B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	144	132		
Units: Percentage of subjects				
number (not applicable)				
Pertussis toxoid; Pre-vaccination	84	79.5		
Pertussis toxoid; 1 month Post-vaccination	100	100		
Pertussis toxoid; 3 years Post-vaccination	96.4	96.2		
Pertussis toxoid; 5 years Post-vaccination	98.3	94.2		
Pertussis toxoid; 10 years Post-vaccination	71.6	76.9		
Filamentous hemagglutinin; Pre-vaccination	99.3	98.5		
Filamentous hemagglutinin; 1 month Post-vaccination	100	100		
Filamentous hemagglutinin; 3 years Post-vaccination	100	100		
Filamentous hemagglutinin; 5 years Post-vaccination	100	100		
Filamentous hemagglutinin; 10 year Post-vaccination	98.9	97.5		
Pertactin; Pre-vaccination	79.9	81.8		
Pertactin; 1 month Post-vaccination	100	100		
Pertactin; 3 years Post-vaccination	99.1	100		

Pertactin; 5 years Post-vaccination	98.3	99		
Pertactin; 10 years Post-vaccination	95.6	97.5		
Fimbriae; Pre-vaccination	79	86.3		
Fimbriae; 1 month Post-vaccination	100	100		
Fimbriae; 3 years Post-vaccination	99.1	99		
Fimbriae; 5 years Post-vaccination	100	98.1		
Fimbriae; 10 years Post-vaccination	96.7	97.5		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects with Seroprotection to Poliovirus Antigens Following Vaccination with Either TdcP-IPV or TdcP-IPV and Hepatitis B Vaccine Given Concurrently

End point title	Percentage of Subjects with Seroprotection to Poliovirus Antigens Following Vaccination with Either TdcP-IPV or TdcP-IPV and Hepatitis B Vaccine Given Concurrently
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End point description:

Anti-poliovirus types 1, 2, and 3 titers were measured by a neutralization assay. Seroprotection was defined as antibody titers $\geq$ 1:8 dilution.

End point type	Other pre-specified
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End point timeframe:

Day 0 (pre-vaccination) and 1 month and 3, 5, and 10 years post-vaccination

End point values	Group 1: Tdcp-IPV/Hepatitis B	Group 2: Tdcp-IPV and Hepatitis B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	144	132		
Units: Percentage of subjects				
number (not applicable)				
Poliovirus 1; Pre-vaccination	97.2	98.5		
Poliovirus 1; 1 month Post-vaccination	100	100		
Poliovirus 1; 3 years Post-vaccination	100	100		
Poliovirus 1; 5 years Post-vaccination	100	100		
Poliovirus 1; 10 years Post-vaccination	100	100		
Poliovirus 2; Pre-vaccination	100	100		
Poliovirus 2; 1 month Post-vaccination	100	100		
Poliovirus 2; 3 years Post-vaccination	100	100		
Poliovirus 2; 5 years Post-vaccination	100	100		
Poliovirus 2; 10 years Post-vaccination	100	100		
Poliovirus 3; Pre-vaccination	95.1	95.5		
Poliovirus 3; 1 month Post-vaccination	100	100		
Poliovirus 3; 3 years Post-vaccination	100	100		
Poliovirus 3; 5 years Post-vaccination	100	100		
Poliovirus 3; 10 years Post-vaccination	100	100		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Summary of Geometric Mean Titers of Poliovirus Antibodies Following Vaccination with Either TdcP-IPV or TdcP-IPV and Hepatitis B Vaccine Given Concurrently

End point title	Summary of Geometric Mean Titers of Poliovirus Antibodies Following Vaccination with Either TdcP-IPV or TdcP-IPV and Hepatitis B Vaccine Given Concurrently
End point description:	Anti-poliovirus types 1, 2, and 3 titers were measured by a neutralization assay.
End point type	Other pre-specified
End point timeframe:	Day 0 (pre-vaccination) and 1 month and 3, 5, and 10 years post-vaccination

End point values	Group 1: Tdcp-IPV/Hepatitis B	Group 2: Tdcp-IPV and Hepatitis B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	144	132		
Units: Titers (1/dil)				
geometric mean (confidence interval 95%)				
Poliovirus 1; Pre-vaccination	134.96 (102.43 to 177.82)	149.05 (111.01 to 200.14)		
Poliovirus 1; 1 month Post-vaccination	65216.88 (49464.4 to 85985.9)	38157.97 (29955.97 to 48605.7)		
Poliovirus 1; 3 years Post-vaccination	3720.46 (2875.49 to 4813.73)	2751.55 (2082.42 to 3635.68)		
Poliovirus 1; 5 years Post-vaccination	993.08 (809.3 to 1218.6)	858.5 (702.21 to 1049.56)		
Poliovirus 1; 10 years Post-vaccination	883.71 (701.3 to 1113.57)	873.49 (703.25 to 1084.93)		
Poliovirus 2; Pre-vaccination	271.22 (216.94 to 339.08)	306.04 (251.16 to 372.92)		
Poliovirus 2; 1 month Post-vaccination	152485.2 (115163.6 to 201901.7)	90280.15 (71624.22 to 113795.3)		
Poliovirus 2; 3 years Post-vaccination	10756.89 (8104.16 to 14277.94)	8928.76 (6640.15 to 12006.17)		

Poliovirus 2; 5 years Post-vaccination	2296.33 (1827.35 to 2885.67)	2168.22 (1749.3 to 2687.46)		
Poliovirus 2; 10 years Post-vaccination	1429.53 (1111.05 to 1839.31)	1277.51 (988.26 to 1651.42)		
Poliovirus 3; Pre-vaccination	48.64 (38.32 to 61.75)	45.97 (36.95 to 57.2)		
Poliovirus 3; 1 month Post-vaccination	230898.8 (174414 to 305676.4)	136695.4 (104880.7 to 178161)		
Poliovirus 3; 3 years Post-vaccination	5827.34 (4431.04 to 7663.63)	5411.71 (4021.19 to 7283.07)		
Poliovirus 3; 5 years Post-vaccination	846.01 (664.4 to 1077.27)	825.26 (641.97 to 1060.89)		
Poliovirus 3; 10 years Post-vaccination	758.31 (584.66 to 983.55)	782.8 (583.55 to 1050.08)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

This was a long-term immunogenicity follow-up study of subjects who participated in a previous study, Td9809. No vaccines were administered in this study and adverse event data were also not collected.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	10
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Frequency threshold for reporting non-serious adverse events: 5 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: This was a long-term immunogenicity follow-up study of subjects who participated in a previous study, Td9809. No vaccines were administered in this study and adverse event data were also not collected

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 May 2001	Details regarding the planned long-term follow-up serology studies were included which also involved the collection of additional blood samples at 1, 3, 5, and 10 years post-vaccination.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/25540274>